CLAIMS

1. A method for the preparation of an osteoinductive agent including the steps of modifying a naturally occurring biocompatible biopolymer by subjecting the biopolymer in the solid, or dry state, to a source of ionising radiation in the presence of a mediating gas and annealing the resulting product in the absence of oxygen at a temperature of from 40°C to 120°C to render the product in a dry particulate form; thereafter removing any residual mediating gas; and disposing the product in a hermetically sealed container containing oxygen-free gas.

2. A method according to claim 1 wherein the naturally occurring biocompatible biopolymer is selected from the group consisting of collagen; hyaloronic acid; demineralised bone (DMB); and mixtures thereof.

3. A method according to claim 2 wherein, in the case of the said mixture, the method includes the steps of first subjecting the biocompatible biopolymers to the said source of ionising radiation in the presence of the said mediating gas separately from each other; and thereafter mixing the irradiated biocompatible biopolymers.

4. A method according to claim 2 wherein, in the case of the said mixtures, the method includes the steps of first mixing the biocompatible biopolymers; and thereafter subjecting the mixture to the said source of ionising radiation in the presence of the said mediating gas.

5. A method according to claim 3 or 4 wherein the biocompatible biopolymers are subjected to a minimum absorbed irradiation dose of 16 kGy.

6. A method according to any one of the preceding claims wherein the hermetically sealed container is a secondary container and wherein the method includes the further step of disposing the product inside a first primary container, which is disposed inside the hermetically sealed secondary container.

7. A method according to claim 6 including the further step of providing the first primary container in the form of a syringe - type container, having a plunger for dispensing the contents thereof, and an outlet opening having a diameter larger than 0.6 mm, to allow for the dispensing of the said product in a relatively viscous form.

8. A method according to claim 6 or claim 7 including the further step of filling the space in the first primary container not occupied by the product with the said oxygen-free gas.

9. A method according to any one of claims 6 to 8 which includes the further steps of providing a second primary container; disposing liquid in the second primary container; and disposing the second primary container inside the hermetically sealed secondary container.

10. A method according to claim 9 including the further step of providing the said liquid in the form of pyrogen-free water.

11. A method according to claim 9 or 10 which includes the further step of disposing the hermetically sealed secondary container inside a hermetically sealed tertiary container.

12. A method according to claim 11 including the further step of filling the tertiary container with oxygen-free gas and capturing the oxygen-free gas inside the hermetically sealed tertiary container.

13. A method according to claim 11 or 12 wherein the steps of providing the secondary and tertiary containers include the step of vacuum forming these containers from a radiation stabilised, gas - impermeable material.

14. A method according to any one of claims 9 to 13 including the further steps of subjecting the said containers and their contents, in kit form, to a terminal radiation sterilisation process.

15. A method according to claim 14 wherein the sterilisation process includes the step of subjecting the containers and their contents to a minimum absorbed irradiation dose of 25 kGy.

16. A method according to claim 14 or 15 which includes the further step of opening the sealed containers and mixing the said sterile liquid with the said product in a dry particulate form to hydrate the product to form an osteoinductive agent in the form of a pliable viscous putty.

17. A method according to claim 16 which includes the further step of dispensing the osteoinductive agent from the first primary container to a bone reconstruction site.

18. A method according to any one of the preceding claims including the step of providing the oxygen-free gas in an inert form.

19. A method according to claim 18 including the further step of providing the said gas in the form of nitrogen.

20. A method according to any one of the preceding claims wherein the said mediating gas is selected from the group consisting of acetylene, ethylene and propylene.

21. A kit for preparing and dispensing an osteoinductive agent including a modified naturally occurring biocompatible biopolymer which was subjected, in the solid, or dry state, to a source of ionising radiation in the presence of a mediating gas and annealed in the absence of oxygen at a temperature of from 40°C to 120°C to render the product in a dry particulate form, the product being disposed in a hermetically sealed container containing oxygen-free gas.

22. A kit according to claim 21 wherein the naturally occurring biocompatible biopolymer is selected from the group consisting of collagen; hyaloronic acid; demineralised bone (DMB); and mixtures thereof.

23. A kit according to claim 22 wherein, in the case of the said mixture, the biocompatible biopolymers are subjected in the presence of the said mediating gas to the said source of ionising radiation separately from each other and thereafter mixed.

24. A kit according to claim 22 wherein, in the case of the said mixture, the biocompatible biopolymers are first mixed and thereafter subjected to the said source of ionising radiation in the presence of the said mediating gas.

25. A kit according to claim 23 or 24 wherein the biocompatible biopolymers are subjected to a minimum absorbed irradiation dose of 16 kGy.

26. A kit according to any one of claims 21 to 25 wherein the sealed container is a secondary container and wherein the product is disposed inside a first primary container, which is disposed inside the sealed secondary container.

27. A kit according to claim 26 wherein the first primary container is in the form of a syringe - type container, having a plunger for dispensing the contents thereof and an outlet opening having a diameter larger than 0.6 mm, to allow for the dispensing of the product in a relatively viscous form.

28. A kit according to claim 26 or 27 wherein the space in the primary container not occupied by the product is filled with the said oxygen-free gas.

29. A kit according to any one of claims 26 to 28 which includes a second primary container containing a liquid and being disposed inside the hermetically sealed secondary container.

30. A kit according to claim 29 wherein the liquid is in the form of pyrogen-free water.

31. A kit according to claim 29 or 30 wherein the hermetically sealed secondary container is disposed inside a hermetically sealed tertiary container.

32. A kit according to claim 31 wherein the tertiary container is filled with oxygen-free gas.

33. A kit according to claim 32 wherein the secondary and tertiary containers are vacuum formed from a radiation stable, gas - impermeable material.

34. A kit according to any one of claims 29 to 33 wherein the said containers are subjected, in kit form, to a terminal radiation sterilisation process.

35. A kit according to any one of claims 21 to 34 wherein the oxygen-free gas is inert.

36. A kit according to claim 35 wherein the gas is nitrogen.

37. A kit according to any one of claims 21 to 36 wherein the said mediating gas is selected from the group consisting of acetylene, ethylene and propylene.

38. A method of reconstructive bone surgery in humans or animals including the steps of providing the kit in according to claim 34; opening the secondary and tertiary containers; hydrating the dry particulate product by injecting the sterile liquid into the first primary container and mixing the liquid and the product to form a putty; dispensing the putty into a bone reconstruction site; and closing the site to allow bone reconstruction to take place.

39. An osteoinductive agent prepared in accordance with any one of claims 1 to 20.

40. A method for the preparation of an osteoinductive agent substantially as herein described with reference to the accompanying drawings.

41. A kit for preparing and dispensing an osteoinductive agent substantially as herein described and as illustrated in the accompanying drawings.